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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/693538-Conf. #4018
	Filing Date	October 23, 2003
	First Named Inventor	Michele SANICOLA-NADEL
	Art Unit	1643
	Examiner Name	P. K. Tungaturthi
Total Number of Pages in This Submission	Attorney Docket Number	BGNA117CN

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard PTO form SB/08 Certificate of Mailing Copies of Eighteen (18) References
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	LAHIVE & COCKFIELD, LLP		
Signature			
Printed name	Jill A. Mello, Ph.D.		
Date	February 6, 2006	Reg. No.	55,450

Express Mail Label No. EV244882724US Dated: February 6, 2006



Application No. (if known): 10/693538

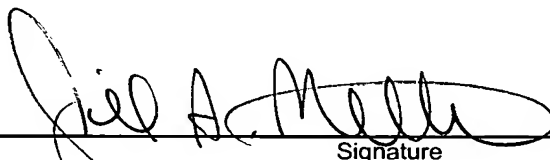
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PTO form SB/08 (23 References) (2 pages)  
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Express Mail Label No. EV244882724US Dated: February 6, 2006

Docket No.: BGNA117CN  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Michele Sanicola-Nadel *et al.*

Application No.: 10/693538

Confirmation No.: 4018

Filed: October 23, 2003

Art Unit: 1643

For: **CRIPTO BLOCKING ANTIBODIES AND  
USES THEREOF**

Examiner: P. K. Tungaturthi

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application in accordance with 37 CFR 1.98(a)(2)(ii). Applicant submits herewith copies of foreign patents and non-patent references in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080, under Order No. BGNA117CN. A duplicate copy of this paper is enclosed.

Dated: February 6, 2006

MEW/JAM/mch

Respectfully submitted,

By 

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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/693538-Conf. #4018
Filing Date	October 23, 2003
First Named Inventor	Michele SANICOLA-NADEL
Art Unit	1643
Examiner Name	P. K. Tungaturthi
Attorney Docket Number	BGNA117CN

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1*	US-5,256,643	10-26-1993	Persico et al.	
	A2*	US-5,264,557	11-23-1993	Salomon et al.	
	A3*	US-5,654,140	08-05-1997	Persico et al.	
	A4*	US-5,792,616	08-11-1998	Persico et al.	
	A5*	US-20040176576-A1	09-09-2004	McKenzie et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B1	WO-00/06723-A1	02-10-2000	Yeda Research and Development Company Ltd. at the Weizmann Institute of Science		
	B2	WO-00/63693-A1	10-26-2000	Kokolus, William, J.		
	B3	WO-02/22808-A2	03-21-2002	Biogen, Inc.		
	B4	WO-02/059620-A2	08-01-2002	The Government of the United States of America		
	B5	WO-02/077033-A1	10-03-2002	The Austin Research Institute		
	B6	WO-03/083041-A2	10-09-2003	Sanicola-Nadel, Michele, et al.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Bianco, Caterina, et al., "Cripto-1 Indirectly Stimulates the Tyrosine Phosphorylation of <i>erb</i> B-4 through a Novel Receptor," <i>The Journal of Biological Chemistry</i> , Vol. 274(13):8624-8629 (1999)	
	C2	Brandt, Ralf, et al., "Identification and Biological Characterization of an Epidermal Growth Factor-related Protein: Cripto-1," <i>The Journal of Biological Chemistry</i> , Vol. 269(25):17320-17328 (1994)	
	C3	Ciardello, Fortunato, et al., "Inhibition of CRIPTO expression and tumorigenicity in human colon cancer cells by antisense RNA and oligodeoxynucleotides," <i>Oncogene</i> , Vol. 9:291-298 (1994)	
	C4	Ciccociola, Alfredo, et al., "Molecular characterization of a gene of the 'EGF family' expressed in undifferentiated human NTERA2 teratocarcinoma cells," <i>The EMBO Journal</i> , Vol. 8(7):1987-1991 (1989)	
	C5	Dublin, Edwin A., et al., "Amphiregulin and cripto overexpression in breast cancer: relationship with prognosis and clinical and molecular variables," <i>International Journal of Oncology</i> , Vol.	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Art Unit	1643
				Examiner Name	P. K. Tungaturthi
Sheet	2	of	2	Attorney Docket Number	BGNA117CN

		7:617-622 (1995)	
	C6	Ebert, Andreas D., et al., "Cripto-1 Induces Phosphatidylinositol 3'-Kinase-dependent Phosphorylation of AKT and Glycogen Synthase Kinase 3 $\beta$ in Human Cervical Carcinoma Cells," <i>Cancer Research</i> , Vol. 59:4502-4505 (1999)	
	C7	Kannan, Subha, et al., "Cripto Enhances the Tyrosine Phosphorylation and Shc and Activates Mitogen-activated Protein Kinase (MAPK) in Mammary Epithelial Cells," <i>The Journal of Biological Chemistry</i> , Vol. 272(6):3330-3335 (1997)	
	C8	Normanno, Nicola, et al., "Expression of amphiregulin, cripto-1, and heregulin $\alpha$ in human breast cancer cells," <i>International Journal of Oncology</i> , Vol. 2:903-911 (1993)	
	C9	Saeki, Toshiaki, et al., "Expression of cripto-1 in human colorectal adenomas and carcinomas is related to the degree of dysplasia," <i>International Journal of Oncology</i> , Vol. 5:445-451 (1994)	
	C10	Saeki, Toshiaki, et al., "Immunohistochemical detection of cripto-1, amphiregulin and transforming growth factor alpha in human gastric carcinomas and intestinal metaplasias," <i>International Journal of Oncology</i> , Vol. 5:215-223 (1994)	
	C11	Salomon, D.S., et al., "The EGF-CFC family: novel epidermal growth factor-related proteins in development and cancer," <i>Endocrine-Related Cancer</i> , Vol. 7:199-226 (2000)	
	C12	International Search Report Application No. PCT/US02/11950, dated September 5, 2003	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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